

## **REMARKS**

The Office Action mailed September 08, 2006, has been carefully reviewed. Claims 26, 31, and 32 stand amended. Claim 34 is newly added. Claim 30 is canceled and claims 1- 25 stand canceled. The amendments to the claims are to more precisely and distinctly claim the subject matter of the invention.

Claims 31 and 32 stand rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1-14 of U.S. Patent No. 6, 713, 070.

Claim 30 is objected to as depending from a rejected base claim but is otherwise deemed free of the cited prior art.

Claim 31 is objected to for grammatical error.

Claim 32 is objected to for failure to identify the full names of the acronyms, “gB” and “gH”.

Claims 26, 27, and 33 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Michel et al. (1996) in view of Gibson et al. (1984).

Claims 28 and 29 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Michel et al. (1996) in view of Gibson et al. (1984), and further in view of Uyttersprot et al. (1998).

Claims 31 and 32 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Gibson et al. (1984), in view of Plachter et al. (1998) and Wills et al. (1996).

The claims as amended herein are fully supported by the application as originally filed. No new matter has been added. Reexamination, reconsideration, and allowance of the present application are respectfully requested in view of the foregoing amendments and the following additional remarks.

### Double Patenting Rejection

Claims 31 and 32 stand rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1-14 of U.S. Patent No. 6, 713, 070. In order to advance the prosecution of the instant invention, Applicant files herewith a Terminal Disclaimer in order to obviate this ground for rejection and respectfully asks that it be withdrawn.

### Claim Objections

Claim 30 is objected to as depending from a rejected base claim but is otherwise deemed free of the cited prior art. Claim 31 is objected to for grammatical error. Claim 32 is objected to for failure to identify the full names of the acronyms, “gB” and “gH”.

The claims have been amended to obviate these objections and it is respectfully requested that they be withdrawn.

### Rejections Under 35 U.S.C. § 103(a)

Claims 26, 27, and 33 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Michel et al. (1996) in view of Gibson et al. (1984).

As amended, the limitations of allowable claim 30, now canceled, have been incorporated into claim 26. This ground for rejection is now moot and it is respectfully requested that it be withdrawn.

Claims 28 and 29 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Michel et al. (1996) in view of Gibson et al. (1984), and further in view of Uyttersprot et al. (1998).

As amended, the limitations of allowable claim 30, now canceled, have been incorporated into independent claim 26 from which both claims 28 and 29 depend. This ground for rejection is now moot and it is respectfully requested that it be withdrawn.

Claims 31 and 32 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Gibson *et al.* (1984), in view of Plachter *et al.* (1990) and Wills *et al.* (1996) (sic). The Examiner probably meant Reschke *et al.*, instead of Wills *et al.*

According to the Examiner, Gibson *et al.* describe the isolation of noninfectious HCMV particles including dense bodies, which are devoid of capsids and contain less than trace amounts of viral DNA but contain all of the glycoprotein species present in virions. Specifically, the Examiner believes that Gibson *et al.* describe the use of the noninfectious viral particles as subunit vaccines.

The Examiner asserts that Gibson *et al.* is deficient in not teaching sub-viral particles containing a pp65 fusion protein. The Examiner claims that said deficiency in Gibson *et al.* is cured by Plachter *et al.* which allegedly describe fusion protein resulting from fusing different fragments of the open reading frame coding for pp65 with fragments from purified lambda clones.

The Examiner further asserts that Reschke *et al.* describe humoral immune response to gpUL75 (gH) and constitutive expression of HCMV gH protein in astrocytoma cells and as such it would have been obvious to one of skill in the art to modify the dense bodies of Gibson *et al.* by adding pp65 fused to the gH protein. The Examiner believes that the motivation for making the combination deemed obvious by the Examiner is to increase immunogenicity by eliciting

both humoral and CTL immune response and that there would be reasonable expectation of success given that pp65 and gH proteins can be stably expressed in mammalian cell lines as taught by Plachter et al. and Reschke et al. Applicant respectfully disagrees and now traverses as follows.

The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that the process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art ... Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure. In re Dow Chemical Co. 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988). In fact, to draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge: is to use the invention as a template for its own reconstruction.

Seasonics, Inc. v. Aerosonic Corp., 81 F.3d 1566, 38 USPQ2d 1551 (Fed. Cir. 1996).

To that extent, Applicant finds the asserted combination of Gibson *et al.* (1984), Plachter *et al.* (1990) and Reschke *et al.*, quite improper since a close reading of the cited arts does not suggest the invention herein claimed nor the likelihood of success.

Plachter *et al.* describe the prokaryotic expression of tegument protein pp65 of HCMV as fusion protein with  $\beta$ -galactosidase, **(and not as the Examiner wrongly asserts, with purified lambda clones)** merely as an expression and isolation facilitator in a prokaryotic expression system. Expressly, the objective of Plachter et al. "was to clone and express parts of pp65 in bacterial high-level expression vectors to obtain defined antigens representing immunodominant epitopes of this protein. ..." See Page 1233, Right Col., Third Paragraph. The fact that pp65 was produced by Plachter et al. in a bacterial expression system, without suggestion whatsoever that it can also be practiced with a mammalian expression system makes it an improper combination for obviousness-type rejection.

The Examiner is particularly referred to the last paragraph on page 1234 of Plachter et al. which reads as follows: "The results of this study, however, indicate that pp65 alone is not a

reliable antigen to use as a **diagnostic tool** but might be very helpful in combination with other antigens for the detection of acute stages of HCMV infections." Plachter et al., teaches use of pp65 as a serodiagnostic tool. There is no suggestion or teaching in Plachter et al. to use fusion proteins comprising pp65 in the manner claimed in the present invention to immunize patients against HCMV diseases.

Not only is the combination improper, the combined art of Gibson *et al.*, Plachter *et al.* and Reschke *et al.* still does not teach the elements of the claimed invention. Reschke *et al.* relates to the expression of human cytomegalovirus glycoproteins gpUL75 (gH) in astrocytoma cells and further studied the specific humoral immune response to gH. Applicant is at a great loss on how Reschke et al. can possibly cure the admitted deficiency of Gibson et al. to lack of sub-viral particles containing pp65 fusion protein expressed in a mammalian system. Since this deficiency is neither cured by Reschke et al. or by Plachter et al., there is no basis for maintaining this ground for rejection and it is respectfully requested that it be withdrawn.

### Conclusion

In view of the foregoing remarks, Applicants submit that there is no basis for applying the previous rejections to the pending claims and withdrawal of the rejections is respectfully requested. The claims are believed to be in condition for allowance, and Applicant earnestly solicits from the Examiner early notification of allowability.

Should the Examiner have any questions or believe a personal or telephonic interview may be in order, he is invited to contact the undersigned at his earliest convenience.

Respectfully submitted,

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